K101143

HEARTWAY MEDICAL PRODUCTS CO.,LTD.
NO.6, ROAD 25, TAICHUNG INDUSTRIAL PARK, TAICHUNG, TAIWAN R.O.C. 408
TEL: 886-4-23580357 (Sales) 23583232 (Rep) FAX: 886-4-23590786
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HEARTWAY

MAY 2 5 2010

" 510(k) SUMMARY "

Submitter's Name: ***HEARTWAY Medical Products Co., Ltd.***
No.6, Road 25, Taichung Industrial Park, Taichung, 40850, Taiwan, ROC

Date summary prepared: April 15, 2010

Device Name:

Proprietary Name:	HEARTWAY Power Mobility Scooter, S11
Common or Usual Name:	POWERED SCOOTER
Classification Name:	MOTORIZED 4-WHEELED VEHICLE, Class II, 21 CFR 890.3800
Product Code:	INI

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The HEARTWAY Power Mobility Scooter, S11 is an indoor / outdoor electric scooter that is battery operated. It has a base with four-wheeled with a seat, armrests, and a front basket. The movement of the scooter is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically powered wheelchairs, scooters, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

HEARTWAY Power Mobility Scooter, PF6 (K072104)

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Summary for substantial equivalence comparison:

According to the above table that the intended use between the two devices is the same. Mainframes materials of the two devices are fixed, and all meet the strength and fatigue tests and they use the same material aspects. Moreover, the suspension of cross brace, footplates, incline degree 10°, and armrest type are all the same. The back upholstery material is also the same fabric and passed the resistance ignition test.

Especially the electronic systems between two devices are the same suppliers, and all passed by the UL certificated, for instance the electronic controller, batteries, and the competent switches and switching power supplies. Thus the same safety level for the two devices is assured.

Owing to the new device is more agile and easy for storage or transportation and the predicate device is more general use. Besides, the new device has a "free-wheel" manual feature that means the new device can be moved without turning it on. Free-wheeling is accomplished by adjusting the free-wheeling lever to the free-wheeling position. Thus the main difference for the two devices is overall appearance, weight capabilities, maximum speed, and the weight are differences between the two devices. The safety levels of the two devices are the same and the overall appearance differences are not safety aspect. They are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Heartway Medical Products Co., Ltd.
% ROC Chinese-European Industrial Research Society
Dr. Ke-Min Jen
No. 58, Fu-Chiun Street
Hsin-Chu City, 30067, Taiwan
Republic of China

MAY 2 6 2010

Re: K101143
Trade/Device Name: HEARTWAY Power Mobility Scooter, S11
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: April 9, 2010
Received: April 22, 2010

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

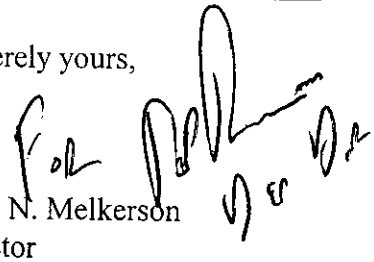
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): K

Device Name: *HEARTWAY Power Mobility Scooter, S11*

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101143